

REMARKS

The Office Action dated January 6, 2005, has been carefully considered. The applicants' attorney thanks the Examiner for the teleconference of June 1, 2005. Claims 1, 4, 19, 20, 37, 32, 33 and 42 have been amended. Claims 6, 34, 43-46 have been canceled. Claims 1, 4, 5, 7-33, 35, 36, 38-42 and 47 are in this application.

Claim 1 has been amended to include the limitations of claims 43-46. No new matter has been entered.

The claims were rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Examiner indicated that only the water-soluble component of the polymeric matrix dissolves in water and not the whole matrix disintegration. Applicants submit that amended claim 1 provides a single polymeric matrix layers consist of a bioadhesive water-soluble film forming polymer. Each of the materials selected from the water-soluble film forming polymer are water-soluble as shown throughout the specification and in particular in the Examples. Accordingly, the single polymeric matrix layer consisting of the bioadhesive water-soluble film forming polymer dissolves or disintegrates in the presence of water as described on page 5, line 19 through page 6, line 5. To further prosecution, claims 6 and 34 have been canceled and the anti-dandruff agent has been canceled from claims 27 and 32.

The previously presented claims 1, 5, 7, 9, 11, 14, 15, 18-24, 26, 27 and 30-36 were rejected under 35 U.S.C. § 102 as anticipated by previously cited PGPUB 2001/0007671 to Gueret ("Gueret '671").

The Examiner stated that the cited matrix has the same polymeric materials as the instantly claimed patch and inherently will have the properties of solubility in water or adhesions to the skin. Applicants respectfully submit that Gueret '671 does not teach a patch consisting of the water-soluble film polymer materials defined in the present claims. Rather, Gueret '671 discloses a patch formed of a composition including a hydrophilic gelling system including a gellan gum and at least one other hydrocolloid. The patch does not disintegrate when it is removed from the skin. Col. 1, paragraph [0015]. However, Gueret '671 does not disclose or suggest that a patch consisting of a single polymeric matrix layer formed of a water-soluble film forming polymer consisting of one or more materials selected from the group consisting the

carbohydrate, maltodextrins, polyvinyl alcohol, polyvinyl pyrrolidone, modified starch derivatives, starch derivatives, modified starches, starch hydrolyzate, hydroxyalkyl starches, hydroxypropyl cellulose, and hydrolyzed starch and a combination thereof. Instead, Gueret '671 teaches a water insoluble hydrophilic gelling system including at least one gellan gum and at least one other hydrocolloid. There is no teaching or suggestion in Gueret '671 of the use of a water-soluble film forming polymer without the use of a gellan gum. Rather, Gueret '671 teaches the use of a gellan gum for forming a hydrophilic gelling system. Accordingly, each limitation of the present claims is not found in Gueret '671 and the invention defined by the present claims is not anticipated by Gueret '671.

The previously presented claims 1, 4, 5, 8, 9, 11, 13-15, 18, 20-25, 27-33, 35, 36 and 42 were rejected under 35 U.S.C. § 102(e) as anticipated by previously cited U.S. Patent No. 6,419,935 to Gueret ("Gueret '935").

Gueret '935 discloses a cosmetic skin treatment method in which a patch is configured to be used in both a cleansing mode and a treatment mode. The patch includes a polymeric matrix and a reinforcing member. When the cleansing mode is selected the patch is adhered to dry skin with an adhesive for a time sufficient to allow an impurity in the area of the skin to become attached to the polymeric matrix. After the impurity is attached, the patch is removed from the skin. When the treatment mode is selected, a cosmetically active agent is dissolved upon application of moisture and the patch is removed from the area of the skin.

In contrast to the invention defined by the present claims, Gueret '935 does not teach or suggest a patch consisting of a single polymeric layer formed of a bioadhesive water-soluble film forming polymer. Rather, Gueret '935 teaches that the patch includes an adhesive layer for adhering the patch to dry skin. Further, Gueret '935 teaches a patch formed of the polymeric matrix and a reinforcing member of a thermoplastic. However, Gueret '935 does not teach or suggest that the patch is configured such that a single polymeric matrix layer adheres the patch to the skin without the use of an adhesive and that the polymeric matrix layer dissolves or disintegrates for removing the patch. Accordingly, Gueret '935 does not teach or suggest a patch consisting of a single polymeric layer. Applicants submit that the single polymeric layer of the present invention has the advantage that the patch dissolves or disintegrates in the presence of

water. In contrast, Gueret '935 teaches away from the present invention by teaching a thermoplastic reinforcement member which does not dissolve or disintegrate in the presence of water. Accordingly, each limitation of the present claims is not found in Gueret '935 and the invention defined by the present claims is not anticipated by Gueret '935.

The previously presented claims 1, 8-14, 16-18, 22, 24, 26, 27, 30, 32 and 38-40 were rejected under 35 U.S.C. § 102(e) as anticipated by previously cited U.S. Patent No. 6,586,000 to Luo et al.

Luo et al. disclose a drug delivery system including the use of a topical or transdermal patch wherein the active agent is contained within a laminated structure that is to be affixed to the skin. In such a structure, the drug composition is contained in a layer, or reservoir underlying an upper backing layer. In one embodiment, the reservoir comprises a polymeric matrix of a pharmaceutically acceptable adhesive material that serves to affix the system to the skin during drug delivery; typically, the adhesive material is a pressure-sensitive adhesive (PSA) that is suitable for long-term skin contact, and which should be physically and chemically compatible with the active agent, hydroxide-releasing agent, and any carries, vehicles or other additives that are present. Alternatively, the reservoir may be comprised of a liquid or semisolid formulation contained in a closed compartment or "pouch" or it may be a hydrogel reservoir, or may take some other form.

In contrast to the invention defined by the present claims, Luo et al. do not teach or suggest a patch consisting of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer. Rather, Luo et al. teach a laminated structure including a reservoir of an adhesive material. Further, Luo et al. teach that an adhesive material affixes the system to the skin during drug delivery.

In addition, Luo et al. discloses that the patch can include a hydrogel reservoir. Applicants submit that hydrogels are macromolecular networks that absorb water and thus swell but do not dissolve in water. However, Luo et al. do not disclose or suggest that the single polymeric matrix layer is formed of a water-soluble film forming polymer one or more materials selected from the group consisting of a carbohydrate, maltodextrins, polyvinyl alcohol, polyvinyl pyrrolidone, modified starch derivatives, starch derivatives, modified starches, starch

hydrolyzate, hydroxyalkyl starches, hydroxypropyl cellulose, and hydrolyzed starch and a combination thereof. Further, Luo et al. includes a backing layer which is inert and incapable of absorbing drugs and does not provide a patch consisting of a single polymeric matrix layer. Accordingly, each limitation of the present claims is not found in Luo et al. and the invention defined by the present claims is not anticipated by Luo et al.

Claim 7 was rejected under 35 U.S.C. § 103 as being obvious in view of Gueret '935 in combination with U.S. Patent No. 5,322,695 to Shah et al. or Luo et al. in combination with Shah et al.

Shah et al. disclose a multilayer pressure sensitive adhesive patch. The patch consists of a polymeric backing and adhering to one surface of the polymeric backing a medication reservoir.

In contrast to the invention defined by the present claims, Shah et al. do not teach or suggest a patch consisting of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer. Rather, Shah et al. disclose a multi layer structure of a thermoplastic polymeric polyvinyl chloride backing material, a medication reservoir which is a mixture of polyvinyl chloride polymeric plasticizer and a topical medicament and a pressure sensitive adhesive. Accordingly, Shah et al. do not cure the deficiencies of Gueret '935 and Luo et al. noted above and the invention defined by the present claims is not obvious in view of Gueret '935 in combination with Shah or Luo et al.

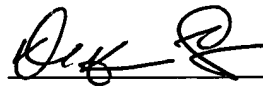
Claim 41 was rejected under 35 USC § 103 as obvious in view of Luo et al. in combination with Gueret '935.

As described above, neither Luo et al. nor Gueret '935 describe or suggest a patch consisting of a single polymeric matrix layer consisting of a bioadhesive water-soluble film forming polymer and the present invention is not obvious in view of the combination of Luo et al. and Gueret '935.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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Diane Dunn McKay
Reg. No. 34,586
Attorney for Applicant

MATHEWS, SHEPHERD, McKAY & BRUNEAU, P.A.
100 Thanet Circle, Suite 306
Princeton, NJ 08540
Tel: 609 924 8555
Fax: 609 924 3036